

## CARRA Data and Sample Sharing Policy

### **Purpose**

This document provides a framework to help investigators access clinical data and/or biosamples collected through CARRA-sponsored research. It is intended to be easy to understand, transparent, and equitable.

### **Scope**

This policy governs data and biosamples collected through CARRA-sponsored research. Examples of such research include the CARRA Registry, CARRA randomized controlled trials, CARRA Consensus Treatment Plan studies, and other studies that use CARRA infrastructure and/or resources. For data or biosamples that fall under the jurisdiction of a specific study PI (e.g. the PI of APPLE), the Data and Sample Share Committee (DSSC) serves in an advisory capacity unless the study PI has transferred the responsibilities for distribution of data and samples to CARRA. This policy does not cover data and biosamples collected and stored by investigators at their own sites for their own use, with their own funds.

### **Types of Requests**

- a) General, basic inquiries or patient cohort counts in support of a grant submission can be requested from CARRA. Formal DSSC review is not required for CARRA to provide this level of information. However the data request does need to be documented in the data and sample share portal for tracking and reporting purposes.
- b) Request for data and/or biosamples to be used for research and publication (full portal submission and DSSC approval required).
- c) Request for a Letter of Support (LOS). LOS guaranteeing access to data and/or biosamples can be issued for applications that have been formally approved. Other LOS, for example: detailing data or samples that are potentially available for a particular project, can be provided by CARRA without formal DSSC review but do not represent a promise that samples or data will be provided.

All requests are to be submitted via the data and sample share portal available on the CARRA website.

### **The CARRA Data and Sample Share Committee**

The DSSC is responsible for evaluating requests for CARRA data and biosamples.

Please see **Addendum 1** for details of the makeup of the DSSC.

### **Process for Submitting Requests:**

1. In order to batch and review requests in a timely manner, the data and sample share portal will accept requests at least quarterly. These submission deadlines will be posted on the CARRA website.
2. A data or sample request is submitted using the CARRA data and sample share portal available on the CARRA website. The submission contains 3 elements:

- a. An Application (PI contact info and proposal details that also includes the data fields being requested based on the study's most recent case report forms (CRFs)) and/or samples being requested. \*Please ensure that the submission specifically addresses study feasibility, including a sample size calculation and evidence that the investigator has appropriate resources and expertise to conduct the study proposed.
- b. NIH Biosketch for PI and major co-investigators (The process for submitting this document is available within the online application).
- c. Documentation of local IRB approval for the study, a waiver for the study, or a statement that IRB approval will be obtained (The process for submitting this information is available within the online application). Data and biosamples will not be released until the applicant provides confirmation of IRB approval or waiver. If IRB approval is not obtained within 6 months of the application approval, resubmission will be required.

### **Process for Reviewing Requests:**

1. DSSC reviews should be completed within 4 weeks of each quarterly deadline.
2. A request to review a high priority proposal may be considered by the DSSC on a case-by-case basis.
3. Document collection, administrative review, and general management of the review process will be conducted by the CARRA Director of Research Operations, who serves in this capacity as a non-voting member of the DSSC.
4. If duplicate and/or overlapping applications are received, the DSSC may ask investigators to collaborate. If investigators are unable to collaborate, all proposals will be scored by the DSSC, with preference going to the best-scoring proposal.
5. Applications will be reviewed and scored based upon the 9-point NIH Peer Review and Scoring Process ([http://grants.nih.gov/grants/peer\\_review\\_process.htm](http://grants.nih.gov/grants/peer_review_process.htm)).
6. The DSSC will give particular consideration to the following applicants:
  - a. Investigators who have contributed to the specific collection to be accessed.
  - b. Investigators from sites with active Registry enrollment.
  - c. Early investigators (EI). For this purpose, EI is defined as anyone at a rank no higher than Assistant Professor who is still developing his or her investigative portfolio and does not yet have funding equivalent to an R01 or other substantial non-mentored investigator award. This includes projects in which an EI (including a fellow) will lead the project, even if the PI is more senior.
7. At least four DSSC members will review each request. These members will be selected based on relevant expertise and absence of conflicts. To ensure optimal use of CARRA data and biosamples, the DSSC may request clarification or revisions from the submitting PI, or solicit additional outside expertise. See addendum 1 for detailed information regarding the makeup of the DSSC.
8. The requestor will be notified by email of the decision of the DSSC.

- A. For requests that are approved:
    - 1. Data Requests:
      - a. The DSSC Administrative Lead notifies the CARRA Data Warehouse Administrator (DWA) and shares the proposal with them.
      - b. The requestor is responsible for making contact with the DWA to ensure the dataset contains the appropriate fields.
      - c. Once the release conditions are met (below), the DWA provides the dataset in the format agreed upon with the requestor
    - 2. Biosample Requests:
      - a. The DSSC notifies the appropriate biosample holder and shares the proposal with them.
      - b. The requestor is responsible for making contact with the biosample holder to ensure the appropriate biosamples are provided.
      - c. Once the release conditions are met (below), the biosample holder ships the biosamples to the requestor.
  - B. For requests that are not approved:
    - 1. The DSSC will provide the requestor with the rationale for why the request was denied.
    - 2. In the event that the requestor disagrees with the decision of the DSSC, he or she may appeal to the CARRA Executive Committee.
9. Applications from non-CARRA members may be considered, including those from commercial entities. However, prior to final approval, these applications will require additional review from the CARRA Executive Committee and legal counsel.

#### **Release Conditions:**

- 1. Research conducted with CARRA data and samples must comply with all applicable laws and ethical principles, as well as CARRA and institutional requirements. These include Health Insurance Portability and Accountability Act (HIPAA) regulations and CARRA policies on ethics and conflict of interest. The principal investigator requesting samples is responsible for compliance. (<http://sourcebook.od.nih.gov/ethic-conduct/ethical-conduct-toc.htm>)
- 2. To facilitate transparency, the name of the PI and the title of approved projects will be posted on the CARRA website.
- 3. Data and samples will not be provided until IRB approval or an appropriate waiver is provided to CARRA. If IRB approval was required, documentation of continued IRB approval must be submitted annually until the project is completed.
- 4. Data and sample transfer must be accomplished under cover of appropriate Data Use Agreements and/or Materials Transfer Agreements.
- 5. The PI must propose a plan that appropriately recognizes the contributions of others, as part of the application which subscribes to the CARRA publication guidelines (see [www.carragroup.org](http://www.carragroup.org) for more info). DSSC approval of an authorship plan does not prejudice the decision of the CARRA Publications Committee to render the final CARRA decision in this

matter. Investigators are encouraged to direct questions to the Publications Committee Chair in advance of submission.

6. Recipients of CARRA data and samples agree to provide primary data derived from these samples to CARRA if so requested by the CARRA Executive Committee. Investigators must provide reasonable access to such datasets to other CARRA investigators. The DSSC will adjudicate requests in a manner consistent with the protection of the interests of all parties.
7. Progress reports are due biannually in March and September of each year until the work is published or concluded. These updates should be titled: "DSSC Brief Update" in the email subject line and sent to [research@carragroup.org](mailto:research@carragroup.org) and may include abstracts, manuscripts, presentations, or other evidence that the project is on track. The DSSC will review these progress reports for adherence to project scope and timeline. If progress is not occurring, then the DSSC will arrange a conference call with the PI to discuss how to improve study progress.
8. Investigators agree to use the data and samples only for the approved research project. If investigators require more data/biosamples and/or have changed the study focus/question, a new application or an addendum (flexible format at the discretion of the PI) must be submitted. The purpose of this policy is to protect other approved investigators.
9. Investigators are responsible for costs associated with aliquoting and shipping samples. If a complex clinical data set is required, a fee may be charged to offset these costs.
10. All resulting publications, including abstracts and manuscripts, must be reviewed by the CARRA Publications Committee prior to submission. Publications must credit CARRA and other relevant sponsors as determined by the CARRA Publications Committee, and for data or samples resulting from the CARRA Registry, the CARRA Registry Investigators and coordinators. Copies of published work must be sent to [research@carragroup.org](mailto:research@carragroup.org). Investigators are responsible for the costs of publication.

## Addendum 1: The CARRA Data and Sample Share Committee

- The CARRA Data and Sample Share Committee (DSSC) has two Co-Chairs: the CARRA Registry Scientific Director and the TRTC Vice Chair.
- The DSSC reports to the CARRA Executive Committee
- At least 4 DSSC voting members will be assigned to review each request. The DSSC will be composed of the following voting members:
  - The CARRA Registry Scientific Director (Serves as DSSC Chair for data requests)
  - One member from the Translational Research and Technology Committee (TRTC) leadership (Vice Chair) with translational, biosample and basic science expertise (Serves as DSSC Chair for sample requests)
  - At least one member from the relevant CARRA disease-specific research committee (JIA, SLE etc.) of which the request pertains to. This reviewer (appointed by DSSC Co-Chairs) will be agreed upon by the Chair and/or Vice Chair of each disease-specific committee and will have:
    - relevant subject matter and clinical expertise,
    - awareness of the relevancy of the request,
    - knowledge if the research request is redundant
  - The CARRA Data Warehouse Administrator (DWA)
- One member from CARRA Inc. will serve as the administrative lead for all submitted requests (No voting privileges).
- If any DSSC reviewer is in conflict or otherwise unavailable, an *ad hoc* member will be appointed by the DSSC Co-Chairs.
- If all members are in conflict, then the Executive Committee will review the submission or will appoint suitable replacements.
- The DSSC will periodically review progress reports which will be provided by the administrative lead.
- Three of the four DSSC voting members are required as a quorum to review a request. These members will be selected based on relevant expertise and absence of conflicts. DSSC decisions are taken by simple majority vote among the reviewers. If the vote was not unanimous, the DSSC administrative lead will follow-up with the 4<sup>th</sup> reviewer not present to obtain their vote. If there is a tie vote, the final decision will be made by the CARRA Executive Committee. It is expected that most DSSC reviews will occur using an online web-based platform where each member can approve, reject or request additional information pertaining to the request. The reviewers may also convene small groups via email or conference call if needed.
- The DSSC Co-Chairs are responsible for determining the review and evaluation criteria for data and sample share requests. These criteria are to be reviewed annually and will be updated as needed.

- The CARRA Director of Research Operations will serve as the administrative lead on the DSSC and will be responsible for:
  - Maintaining accurate proposal deadline dates on the CARRA website
  - Soliciting and collecting applications
  - Making certain that applications are reviewed in a timely manner
  - Enlisting additional expertise as needed (e.g. statistician support)
  - Periodically reviewing DSSC decisions with the CARRA Executive Committee
  - Maintaining records of submissions and approved projects
  - Collecting and distributing project reports
  - Making certain that reports are submitted in a timely fashion
  - Coordinating collection and review of IRB approvals and progress reports
  
- DSSC decisions will be reviewed periodically by the CARRA Executive Committee.